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## VIA ELECTRONIC FILING

February 9, 2006

The Honorable Gregory M. Sleet  
United States District Court  
844 King Street  
Wilmington, DE 19801

Re: Ventana Medical Systems, Inc. v. DakoCytomation California Inc  
C.A. No. 04-1522-GMS



Dear Judge Sleet:

ATLANTA  
AUSTIN  
BOSTON  
DALLAS  
DELAWARE  
NEW YORK  
SAN DIEGO  
SILICON VALLEY  
TWIN CITIES  
WASHINGTON, DC

Pursuant to the Court's Scheduling Order dated March 31, 2005, Defendant DakoCytomation California, Inc. ("Dako") requests permission to move for summary judgment of noninfringement, both literal and by equivalence. As construed by this Court, all of the asserted claims require that the claimed air mixer be positioned next to, but *not above* or beneath where reagents are added and mixed. The air mixer in the accused Artisan® instrument is *above* this zone at all times, and is as required by the claims. Under these circumstances, summary judgment of noninfringement – both literal and under the doctrine of equivalents – is warranted.

### Background

The patent-in-suit, U.S. Patent No. 6,827,901, concerns an automated slide staining instrument. The instrument exposes tissue samples to various chemicals, called reagents, in order to highlight certain features in the sample. The process enables pathologists to diagnose diseases, such as cancer. The patent discloses an instrument that has an air mixer that mixes reagents in a zone on the surface of a slide. The asserted claims all require an air mixer that mixes the reagents on this zone. Importantly the asserted claims all require that the air mixer is "adjacent" this zone and that this mixer direct a jet of air at the zone thereby inducing mixing. (See independent claims 1 and 45.)

On December 13, 2005, the Court construed the term "adjacent" to be "next to, but not above or beneath." (D.I. 56.) This ruling embraced Ventana's own statements during the prosecution of its patent whereby it disclaimed that the word "adjacent" could include above or beneath. The Court's ruling should be dispositive, since the accused Artisan® instrument has an air mixer that is always above the zone where reagents are added and mixed. Indeed the air mixer is

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below. A cross section of the slide and tub is shown

**The Accused Product Does Not Literally Infringe Any Independent Claim of the '901 Patent**

Each of the asserted claims contains the following limitation:

an air mixer comprising an air jet and an air supply means positioned adjacent to a said reagent agitation zone for mixing reagents, said air mixer directing a jet of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

The Court interpreted this limitation such that the air mixer must be positioned next to, but not above or beneath a reagent agitation zone for mixing reagents. That said air mixer must also direct a stream of air at the reagent agitation zone thereby inducing mixing in the reagent agitation zone.

In view of the Court's claim construction, there is no dispute as to where the reagent agitation zone is located in the Artisan® machine (see illustration below).

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The walls of the slide clip define the area (shaded in green) on the slide where reagents are added and mixed. The parties agree that under the Court's claim construction, this area is the reagent agitation zone.

The Artisan® air mixer is pictured below. Air flows out of a narrow slit opening on the bottom of the plenum. This air (shaded in red)

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Throughout this motion, the air mixer remains above the reagent agitation zone. Indeed the plenum is

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Ventana contends that when the narrow slit opening "is in the home position and at the beginning and end of each mixing cycle, the nozzle and the air jet are next to, but not above or beneath the reagent agitation zone as defined by the Court." Ventana is essentially arguing that when the plenum travels past the boundaries of the slide clip, the nozzle and the curtain of air is then adjacent, but not above, as shown in the picture below.

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This is facially flawed. It is clear from the figure that the plenum remains above the reagent agitation zone in each of these locations. However, even if the Court disagrees, summary judgment of noninfringement is still warranted. As indicated previously, all the asserted claims require that the air mixer direct an air jet at the reagent agitation zone and that the air jet induce mixing. Because Ventana has presented no evidence – during either fact or expert discovery<sup>1</sup> that either of these required elements is present when the plenum is in any of these locations, summary judgment of noninfringement is warranted.

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<sup>1</sup> Pursuant to the Courts scheduling order, fact discovery closed on January 13, 2006 and opening expert reports were due on February 1, 2006. Thus Ventana has no further opportunity to expand its infringement allegations.



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As illustrated below, the undisputable facts demonstrate that when the air mixer is in these locations,  
as required by the claims.

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Moreover, Ventana has put forth no evidence showing that any mixing is occurring when the air mixer is next to, but not above, the reagent agitation zone as required by the claims. Ventana's only evidence is the expert report of Dr. Sharon. He cites the Artisan® service manual for the proposition that:

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(Expert Report of Dr. Sharon, at 9 (emphasis added).) This merely shows that the plenum blows air when it is above the slide. However, neither this statement, nor any other evidence that Ventana has produced shows that mixing occurs at the time Ventana alleges the plenum is next to, but not above, the reagent agitation zone.

Under these circumstances Ventana has not and cannot prove literal infringement. Accordingly, summary judgment is appropriate.

**The Accused Product Does Not Infringe Any Independent Claim of the '901 Patent Under the Doctrine of Equivalents.**

The Artisan® staining machine does not infringe the asserted claims '901 patent under the doctrine of equivalents. Ventana's equivalence theory, if correct would vitiate the claim limitation that the air mixer must be next to, but not above, the reagent agitation zone and would run afoul of the doctrine of prosecution history estoppel.

Ventana argues that when the Artisan® air mixer is moving horizontally above the reagent agitation zone, the Artisan® air mixer is equivalent to an air mixer positioned next to, but not above, the reagent agitation zone. Essentially Ventana wants the court to hold that an air mixer positioned above is equivalent to an air mixer positioned not above, or that above is equivalent to not above. This argument would vitiate the required claim limitation of "next to, but not above or beneath." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 39, 117 S.Ct. 1040, 1053, n. 8 (1997) (If applying the doctrine of equivalence "would entirely vitiate a particular claim element, partial or complete [summary] judgment should be rendered

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by the court, as there would be no further *material* issue for the jury to resolve.”) (emphasis original). Claim vitiation would occur especially because the accused product has a feature that is in complete opposition to the claim limitation and specifically excluded from the claim limitation. *Novartis Pharms. Corp. v. Abbott Labs., Inc.*, 375 F.3d 1328, 1337 (Fed.Cir. 2004) (holding that a surfactant cannot be an equivalent of a non-surfactant, when the court construed the claims to require a non-surfactant); *SciMed Life Sys., Inc. v. Advanced Cardiovascular*, 242 F.3d 1337, 1347 (Fed.Cir.2001) (stating that a non-metallic device cannot be an equivalent of a metallic device). Moreover, Ventana’s theory would violate the closely related specific preclusion principle. *Bayer Healthcare LLC v. Abbott Labs.*, 2005 U.S. Dist. LEXIS 21042, \*43 (D. Del. 2005) (“the doctrine of specific exclusion is properly invoked only in special cases, such as where the plaintiff attempts to expand the patent’s claims in a way that defies logic, or in a way that encompasses the exact opposite of what is claimed”). For these reasons, a finding of non-infringement under the doctrine of equivalents is appropriate, as a matter of law.

Next, the doctrine of prosecution history estoppel forecloses the doctrine of equivalents in this case. This Court construed the term “adjacent” to mean “next to, but not above or beneath” in light of statements made by the patentee during the prosecution of the ‘901 patent. Such statements amount to disavowal of subject matter. Accordingly, Ventana should be estopped from arguing that an air mixer positioned above the reagent agitation zone is equivalent to an air mixer positioned next to, but not above or beneath, the reagent agitation zone. When a patentee makes arguments of disclaimer during the prosecution of a patent, the patentee is estopped from trying to recapture the subject matter of the disclaimer. *Day Int’l, Inc. v. Reeves Brothers, Inc.*, 260 F.3d 1343, 1350 (Fed.Cir. 2001) (“Day’s disavowal of the prior art temperatures during the prosecution of the ‘928 patent constitutes prosecution history estoppel, and hence, it should not be allowed to recapture subject matter that it has previously surrendered.”). For this additional reason, a finding of non-infringement under the doctrine of equivalents as a matter of law is appropriate.

Very truly yours,

/s/ Timothy Devlin

Timothy Devlin

cc: Clerk of the Court  
Richard H. Morse (via email and hand delivery)  
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